AUG 2 9 2000

K00 2276

510(k) SUMMARY

Submitter Name:	Pacific Surgical Innovations, Inc.
Submitter's Address:	360 Industrial Road, Unit H San Carlos, CA 94070
Contact Person:	Terry Johnston, VP & General Manager
Phone Number:	650-802-6988
Facsimile Number:	650-802-0120
Date Prepared:	March 12, 2000
Device Trade Name:	PSI Skull Clamp
Device Common Name:	Skull Clamp
Classification Name:	Neurosurgical Head Holder
Predicate Device:	A-1014 Mayfield Skull Clamp Gardner 190-1020 Neurosurgical Skull Clamp.
Device Description:	The PSI Skull Clamp is designed to allow the surgeon freedom in positioning the fixation pins to the skull. Avoidance of critical areas of the skull is made possible by a swiveling rocker arm that rotates 360°, making the final adjustment, after pin impingement, much easier. The skull clamp is supplied with three adult, sterile, single use, disposable steel pins that are easily removed. Reusable pins are also available, if desired. The PSI Skull Clamp is attached to the PSI Base Unit with a swivel adapter.
Intended Use:	Stabilize the patient's head during neurosurgical procedures to include: - Provide 3 point rigid skeletal fixation for the supine, prone, lateral or sitting position. - Provide for craniotomies in all positions. - Provide for Laminectomies (cervical and upper dorsal).

(100)

K002276

Technological Characteristics and Comparison to Predicate	The PSI Skull Clamp is manufactured from the same materials, meeting the same standards and dimensional specifications, as the predicate skull clamps.
Performance Data:	When used in accordance with its directions, as with the predicate device, the PSI Skull Clamp functions in the same manner as the predicate device in safely and effectively positioning and holding the head for appropriate neurosurgical procedures.
Conclusion:	The PSI Skull Clamp is as safe and effective for its intended use as the predicate device, and meets all regulatory requirements to be found substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2000

Mr. Garry L. Cooper
Director of Regulatory Affairs and Quality
Pacific Surgical Innovations, Inc.
360 Industrial Road, Unit H
San Carlos, California 94070

Re: K002276
Trade Name: PSI Skull Clamp
Regulatory Class: II
Product Code: HBL
Dated: July 18, 2000
Received: July 26, 2000

Dear Mr. Cooper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver 3 - 4/24/96

Applicant: **Pacific Surgical Innovations**

510(k) Number (if known): **K002276**

Device Name: **PSI Skull Clamp**

Indications For Use:

STABILIZE PATIENT'S HEAD DURING NEUROSURGICAL PROCEDURES

Including:

3 point rigid skeletal fixation for the supine, prone, lateral or sitting position.

Craniotomies in all positions.

Cervical Laminectomies (upper dorsal approach).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) [signature]

Division of General Restorative Devices

510(k) Number K002276

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)